

07/061,646

PD-3245-C1-01-SMP

EXHIBIT A

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. This volume and accompanying first supplement are current through January 31, 1997.

17TH EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DATABASE MANAGEMENT

1997

PRESCRIPTION DRUG PRODUCT LIST

3-134

ETHINYLYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28		TABLET; ORAL-28		TABLET; ORAL-28	
<u>BREVICON 28-DAY</u>	<u>0.035MG; 0.5MG</u>	N17743	001	BRISTOL MYERS SQUIBB	0.05MG; 1MG
<u>SEARLE</u>		N72695	001	TRI-NORINYL 28-DAY	0.035MG, 0.035MG; 0.5MG, 1MG
<u>AB GENCEPT 0.5/35-28</u>	<u>0.035MG; 0.5MG</u>	FEB 28, 1992			APR 13, 1984
<u>AB GENCON</u>					
<u>AB GENCEPT 1/35-28</u>	<u>0.035MG; 1MG</u>	N72696	001	<u>ETHINYLYL ESTRADIOL; NORETHINDRONE ACETATE</u>	
<u>AB GENCON</u>		FEB 28, 1992			
<u>AB GENCEPT 10/11-28</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>	N72697	001	TABLET; ORAL-21	
<u>AB MODICON 28</u>	<u>0.035MG; 0.5MG</u>	FEB 28, 1992		ESTROSTEP 21	0.02MG, 0.035MG, 0.035MG; 1MG, 1MG
<u>AB NORCEPT-E 1/35 28</u>	<u>0.035MG; 1MG</u>	N17735	001	+ PARKE DAVIS	N20130 001
<u>AB GYNOPHARMA</u>		N71546	001	LOESTRIN 21 1.5/30	OCT 09, 1996
<u>AB NORETHIN 1/35E-28</u>	<u>0.035MG; 1MG</u>	FEB 09, 1989		+ PARKE DAVIS	N17875 001
<u>AB ROBERTS LABS</u>		N71481	001	LOESTRIN 21 1/20	N17876 001
<u>AB WATSON LABS</u>	<u>0.035MG; 0.5MG</u>	APR 12, 1988		+ PARKE DAVIS	
<u>AB WATSON LABS</u>	<u>0.035MG; 0.5MG</u>	N70686	001	TABLET; ORAL-28	
<u>AB</u>	<u>0.035MG; 1MG</u>	JAN 29, 1987		ESTROSTEP FE	0.02MG, 0.035MG, 0.035MG; 1MG, 1MG
<u>AB</u>		N70687	001	+ PARKE DAVIS	N20130 002
<u>AB WATSON LABS</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>	JAN 29, 1987		LOESTRIN FE 1.5/30	OCT 09, 1996
<u>AB WATSON LABS</u>		N71044	001	+ PARKE DAVIS	N17355 001
<u>AB WATSON LABS</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>	APR 01, 1988		LOESTRIN FE 1/20	N17354 001
<u>AB NORINYL 1+35 28-DAY</u>	<u>0.035MG; 1MG</u>	SEP 24, 1991		+ PARKE DAVIS	
<u>AB SEARLE</u>	<u>0.035MG; 1MG</u>	N17565	002	<u>ETHINYLYL ESTRADIOL; NORGESTIMATE</u>	
<u>AB ORTHO-NOVUM 1/35-28</u>	<u>0.035MG; 1MG</u>	N17919	002	TABLET; ORAL-21	
<u>AB JOHNSON RW</u>		N18354	002	ORTHO CYCLEN-21	
<u>AB ORTHO-NOVUM 10/11-28</u>	<u>IN PLASTIC CONTAINER</u>	JAN 11, 1982		+ JOHNSON RW	0.035MG; 0.25MG
<u>AB JOHNSON RW</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>			ORTHO TRI-CYCLEN	DEC 29, 1989
<u>AB + JOHNSON RW</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>	APR 04, 1984		+ JOHNSON RW	0.035MG, 0.035MG, 0.035MG; 0.18MG
<u>AB + JOHNSON RW</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>			0.215MG, 0.25MG	N19697 002
<u>AB + JOHNSON RW</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>			JUL 03, 1992	
<u>AB ORTHO-NOVUM 7/7-28</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>	N19004	002	TABLET; ORAL-28	
<u>JOHNSON RW</u>		APR 04, 1984		ORTHO CYCLEN-28	
<u>AB ORTHO-NOVUM 7/7-28</u>	<u>0.035MG, 0.035MG; 0.5MG, 1MG</u>	N18985	002	+ JOHNSON RW	0.035MG; 0.25MG
<u>JOHNSON RW</u>		APR 04, 1984			DEC 29, 1989
<u>AB OVCON-35</u>	<u>0.035MG; 0.4MG</u>	N17716	001		
<u>AB BRISTOL MYERS SQUIBB</u>	<u>0.035MG; 0.4MG</u>				

PREScription DRUG PRODUCT LIST

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ESTROPIPATE

**TABLET; ORAL
ESTROPIVITATE**

ETIQUETTE CADET

INJECTABLE; INJECTION
EDECRIN
+ MERCK SHARP DOHME

ETHACRYNIC ACID

TABLET: ORAL
EDECIN
MERCK SHARP DOHME
25MG
50MG

ETHAMBITOI: HYDROCHILOBTIDE

N40135 001	TABLET; ORAL		
NOV 27, 1996	MYAMBUTOL	1000MG	N16320 001
	LEDERLE	4000MG	N16320 003
N40135 002	+		
NOV 27, 1996			
N40135 003	ETHANOLAMINE OLEATE		
NOV 27, 1996			
N81213 001	INJECTABLE; INJECTION		
SEP 23, 1993	ETHAMOLIN	50MG/ML	N19357 001
	+ CYPROS		DEC 22, 1988
N81214 001			
SEP 23, 1993			
N81215 001			
SEP 23, 1993			
N81216 001	ETHCHLORYNNOL		
SEP 23, 1993			
N83220 001	CAPSULE; ORAL		
	ETHCHLORYNNOL		
	BANNER PHARMACAPS		
N83220 002	AA	200MG	N84463 002
	AA	500MG	N84463 003
	AA	750MG	N84463 004
N83220 003	AA	1000MG	N84463 001
N83220 004	AA	200MG	N10021 007
	AA	500MG	N10021 002
	AA	750MG	N10021 010
N89567 001	AA		

N89582 001

Ethinodiol
JUL 17, 1951
TABLET: ORAL
ESTINYL
SCHERING
0.02MG
0.05MG
0.5MG
+
N160000 001

EITHINYL ESTRADIOL; "MULTIFLEX"
SEE DESOGESTREL; ETHINYL ESTRADIOL

N05292 001
N05292 002
N05292 003

N18168 001
N16927 001

PRESCRIPTION DRUG PRODUCT LIST

3-231

<u>NITROGLYCERIN</u>		<u>NOREPINEPHRINE BITARTRATE</u>	
AP	INJECTABLE; INJECTION <u>NITRO-BID</u> + HOECHST MARION RSSL	<u>5MG/ML</u>	N18621 001 JAN 05, 1982
AP	<u>NITROGLYCERIN</u> + ABBOTT	<u>5MG/ML</u> <u>5MG/ML</u>	N18531 001 N72034 001 MAY 24, 1988
AP	SMITH AND NEPHEW	<u>5MG/ML</u>	N70633 001 JUN 19, 1986
AP	<u>NITROGLYCERIN IN DEXTROSE 5%</u> ABBOTT	<u>10MG/100ML</u> <u>0.1MG/ML</u>	N71846 001 AUG 31, 1990 N74083 001 OCT 26, 1994
AP		<u>20MG/100ML</u>	N71847 001 AUG 31, 1990
AP		<u>40MG/100ML</u>	N71848 001 AUG 31, 1990 N19970 001 DEC 29, 1989
AP	+ BAXTER HEALTHCARE	<u>10MG/100ML</u>	N19970 002 DEC 29, 1989 N19970 003 DEC 29, 1989
AP		<u>20MG/100ML</u>	MICRONOR + JOHNSON RW 0.35MG
AP		<u>40MG/100ML</u>	N19970 003 DEC 29, 1989 0.35MG
AP	<u>TRIDIL</u> + FAULDING	<u>5MG/ML</u> <u>0.5MG/ML</u>	N18537 001 N18537 002 JUN 16, 1983
OINTMENT; TRANSDERMAL <u>NITROGLYCERIN</u> ALTANA		2%	<u>NORETHINDRONE ACETATE</u>
			N87355 001 JUL 08, 1988
			AB AYGESTIN WIETH AYERST
<u>NIZATIDINE</u>			<u>NORETHINDRONE ACETATE</u> + MULTIPLE*
CAPSULE; ORAL AXID LILLY		150MG 300MG	N19508 001 APR 12, 1988 N19508 002 APR 12, 1988
			AB NORLUTATE + PARKE DAVIS
			5MG 5MG
<u>NORETHINDRONE ACETATE</u> + MULTIPLE*			N18405 001 APR 21, 1982
<u>NORETHINDRONE ACETATE</u> + SEE ETHINYL ESTRADIOL; NORETHINDRONE ACETATE			N12184 002